

### **Remarks/Arguments**

Claims 1, 2 and 8 are pending in this application and are rejected on various grounds. Claims 1 and 8 have been amended to clearly reflect that mdm2 is a p53-binding protein. Support for this amendment is throughout the specification, such as, for example, at page 2, line 13 – page 2, line 4, and page 2, line 23. All amendments are made without any disclaimer or prejudice and do not add new matter.

### **Claim Objection**

Claims 1, 2 and 8 remain objected to for the use of the term “mdm2” “as a sole means of identifying the protein for use in the claimed method, for reasons of record.” In addressing Applicants’ argument that similarly to p53, mdm2 is a well known and generally used name for a known protein, the Examiner states: “Different from p53, mdm2 is not a well known protein. Although several references use the name mdm2, different laboratories may use the same laboratory designations to define completely distinct proteins.”

Applicants disagree. The Examiner has provided no evidence in support of the assertion that mdm2 is not a well known protein. In fact, a PubMed search using “mdm2” as the search term identified 2720 publications, including 276 review articles. Of these, 282 publications were published between 1990 and 1996 and thus preceded the April 22, 1997 priority date of the present application (see enclosed printout, Exhibit A). A PubMed search using “mdm2 and p53” as the search string identified 2374 publications, including 236 review articles. Of these, 233 publications were published between 1992 and 1996 and thus preceded the April 22, 1997 priority date of the present application (see enclosed printout, Exhibit B). In view of this evidence, mdm2 could hardly be called “not a well known protein” at the priority date of the present application. Indeed, the art shows that the “mdm2” designation has been used for many years consistently with its meaning in the present application. However, for avoidance of any doubt, the claims have been amended to refer to “p53-binding protein mdm2,” in order to make the designation absolutely unambiguous.



In view of the foregoing arguments, the Examiner is respectfully requested to reconsider and withdraw the present objection.

**Claim Rejections - 35 USC 103**

Claims 1-2 and 8 were rejected under 35 U.S.C. 103(a) "as being unpatentable over Bottger *et al.*, 1996, *Oncogene*, 13:214-2147, of record, in view of McCann AH *et al.*, 1995, *British J. Cancer*, 71(5):981-5, and further in view of Lee JM *et al.*, 1995, *Cancer and metastasis Review*, 14(2):149-161.

Bottger *et al.* was applied essentially as in the previous Office Action. The Examiner has acknowledged that Bottger *et al.* do not teach SEQ ID NO: 3. The Examiner has also acknowledged that Bottger *et al.* do not teach an in vitro method for disrupting the binding of p53 and mdm2 in a population of cancer cells in which mdm2 is not overexpressed, comprising administering a peptide less than 25 amino acids in length comprising SEQ ID NO: 3.

However, the Examiner has stated that at the time the invention was made, McCann *et al.* taught that protein expression of mdm2 in breast carcinomas was significantly associated with low level of p53, and of note is that most of these tumors have no mdm2 gene amplification. In other words, according to the Examiner, the teaching of McCann *et al.* clearly shows that p53 is suppressed in cancer cells such as breast cancer cells, a majority of which do not overexpress mdm2, which p53 suppression is correlated with the presence of mdm2.

The Examiner has stated that it would have been *prima facie* obvious to use a peptide comprising the 12 amino acid peptide taught by Bottger *et al.* to target cancer cells that express p53 and mdm2 to increase p53 function, including those populations of cancer cells that do not overexpress mdm2, such as in breast cancer cells, as allegedly taught by McCann *et al.*

Applicants respectfully submit that the Examiner has misunderstood and mischaracterized the teaching of McCann *et al.*



As noted in the present application, “cells that do not overexpress mdm2” includes all cells in which mdm2 is present at low or normal levels, which can be assessed, e.g., by immunological measurement of mdm2 concentration (page 6, lines 25-32).

A protein can be overexpressed in a cell for a number of reasons. One possible reason is that the gene expressing the protein is amplified. However, overexpression can also take place in the absence of gene amplification, e.g., due to an alteration in the normal regulation of the rate of synthesis of the protein and/or in the rate of destruction of the protein. Gene amplification is only one of a number of different mechanisms by which overexpression of a protein may occur.

Thus, even where there is no amplification of the gene, the protein may still be overexpressed.

Indeed, McCann *et al.* expressly states that:

Interestingly, at the mRNA level, two studies found increased MDM2 expression with no apparent alteration in MDM2 copy number (Buesco-Ramos *et al.*, 1993; Sheikh *et al.* 1993), suggesting that mechanisms other than gene amplification may play a role in deregulating the expression of MDM2.”

Page 981, right column, first paragraph.

In McCann *et al.*, overexpression at the protein level was assessed by immunological measurement. Seven percent of the samples were found to show 10-50% mdm2 nuclear staining, and these samples were designated as MDM2+ cells. (This is in spite of the fact that only 4% of tumor cells assayed have altered mdm2 copy number – as noted above, overexpression of a protein can occur even without gene amplification).

McCann *et al.* reports that MDM2+ status was significantly associated with low levels of p53 (page 983, left column, last paragraph). As explained above, MDM2+ status indicates overexpression of mdm2. Thus, Applicants submit that the Examiner is wrong to say that McCann *et al.* teach that “in cancers which do not express mdm2, such as breast cancer cells, the protein expression of mdm2 is significantly associated with low levels of p53.” To the contrary, the teaching of McCann *et al.* is that in those samples which show overexpression of mdm2, p53 is reduced.



Bottger *et al.* teaches that the interaction between mdm2 and p53 may be a useful target in cells where mdm2 is overexpressed:

In several different tumour systems, including human sarcomas, the mdm2 protein (or its human homolog hdm2) is overexpressed but the p53 gene remains wild type (Oliver *et al.*, 1992). This suggests that in these tumours the normal tumour suppressor function of p53 is being inactivated by the presence of abnormally high levels of mdm2. In theory, such tumours should be susceptible to therapeutic moieties that disrupt the mdm2/p53 interaction, restoring wild type p53 function.

Page 2141, right column, first paragraph, emphasis added.

Thus, the skilled person reading Bottger *et al.* would believe that therapeutic targeting of the mdm2/p53 interaction is of use specifically in cells where mdm2 is overexpressed. There is nothing in McCann *et al.* to contradict this or to suggest that targeting of the mdm2/p53 interaction may also be of use when mdm2 is not overexpressed.

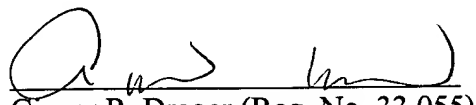
In view of the foregoing arguments, the Examiner is respectfully requested to withdraw the present rejection.

All claims pending in this application are believed to be in *prima facie* condition for allowance, and an early issuance of a Notice of Allowance is respectfully solicited.

Although no fees are believe to be due at this time, please charge any fees, including fees for extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney's Docket No. 39749-0001APC).

Respectfully submitted,

Date: September 18, 2006

  
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
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
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









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



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






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





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
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
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